

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

**This Document Relates to the TPP Trial
Subclasses**

MDL No. 2875

**Honorable Renée Marie
Bumb,
District Judge**

**ZHP DEFENDANTS' RESPONSE TO PLAINTIFFS' TRIAL BRIEF
REGARDING ZHP TRIAL WITNESS TESTIMONY**

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The ZHP Defendants (collectively, “ZHP”) respectfully submit this response to Plaintiffs’ request in their Trial Brief (ECF [2682](#)), that the Court bar ZHP from calling two company employees, Dr. Jinsheng Lin, Ph.D. and Maggie Kong, as trial witnesses. As set forth below, both witnesses were timely disclosed to Plaintiffs more than seven months ago, have been the subject of discovery, and are able to speak to key facts that Plaintiffs have put at issue in this case. Moreover, ZHP, like Plaintiffs, has the right to choose the witnesses it will present at trial. Plaintiffs’ efforts to preclude the testimony of relevant, timely-disclosed ZHP witnesses is thus inappropriate and should be rejected.

As the Court knows, Dr. Lin is the author of the July 27, 2017 email that Plaintiffs have repeatedly asserted is the “smoking gun” in their case against ZHP. Because the meaning of that email, as well as Dr. Lin’s intention in writing it and his knowledge at the time it was sent, are critical issues that are contested by the parties, it would be unfair and unduly prejudicial to bar ZHP from bringing Mr. Lin to directly address these questions at trial.

Similarly, Ms. Kong is the Vice President, Globalization & Development for Zhejiang Huahai Pharmaceutical Co. and has been employed there since 2017. Ms. Kong was directly involved in the company’s response to the discovery of NDMA in Valsartan in 2018 (during which time Ms. Kong was Chief of Staff to the Company’s President) and is therefore well situated to explain the actions taken by

ZHP during that time and respond to Plaintiffs' assertions that those actions were inadequate. Further, and contrary to Plaintiffs' suggestion, ZHP produced documents from Ms. Kong's files responding to Plaintiffs' discovery requests years ago.

In short, Dr. Lin and Ms. Kong are proper witnesses in this case (indeed, Dr. Lin is a critical witness), and Plaintiffs have come nowhere close to establishing that the Court should impose the extreme sanction of barring their testimony at trial.

I. DR. LIN SHOULD NOT BE BARRED FROM TESTIFYING AT TRIAL.

Plaintiffs first seek to preclude Dr. Lin—a research chemist at ZHP's Center of Excellence for Modern Analytical Technologies (“CEMAT”—from testifying at trial. As the Court knows, Dr. Lin authored the July 27, 2017 email that Plaintiffs claim is *central* to their theory of liability with respect to ZHP. ZHP seeks to present Dr. Lin at trial to testify about that email and any other documents that Plaintiffs claim prove that Dr. Lin knew about nitrosamine impurities in ZHP's valsartan active pharmaceutical ingredient (“API”) prior to the discovery of the impurity in 2018.

Throughout this litigation, Plaintiffs have pointed to Dr. Lin's July 27, 2017 email related to a potential impurity in irbesartan—a different medication—as a purported “smoking gun” that supposedly proves that “ZHP knew that its valsartan was contaminated with NDMA” in 2017. (See, e.g., ECF [2569-2](#) at 1.) Nonetheless,

Plaintiffs have never sought to depose Dr. Lin and ask him directly about this email.¹

Now, Plaintiffs want the Court to block the jury from hearing from Dr. Lin based on a frivolous claim that his custodial file is somehow “deficient.” Plaintiffs’ arguments are legally and factually baseless, and barring Dr. Lin from testifying at a trial at which Plaintiffs have made him a central figure would constitute clear error.

It is well established that “each side has the right to present its case through the witnesses it chooses.” *Cassell v. SkyWest, Inc.*, 654 F. Supp. 3d 1222, 1240 (D. Utah 2023) (declining to exclude trial testimony offered by plaintiff’s chosen witnesses because a party “is not entitled to decide which witnesses [its adversary] may call to present its case”); *see also Lewis v. Sw. Airlines Co.*, No. 16-cv-00749-JCS, 2016 WL 3091998, at *6 (N.D. Cal. June 2, 2016) (noting that a defendant “is entitled to present relevant witness testimony in its defense” and a plaintiff cannot “unilaterally determine the scope of evidence”). Consistent with this principle, the Third Circuit has expressed “a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony.” *ABB Air Preheater, Inc. v. Regenerative Env’t Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996) (citing cases); *see also DiFlorio v. Nabisco*

¹ Instead, Plaintiffs have questioned many other ZHP witnesses about Dr. Lin’s email, including those who never received it and had no familiarity with it.

Biscuit Co., No. CIV. A. 95-0089, 1995 WL 710592, at *2 (E.D. Pa. Nov. 13, 1995) (similar) (citing cases).

This is so because the extreme step of excluding critical witness testimony would result in “fundamental unfairness in the trial of the case.” *Newman v. GHS Osteopathic, Inc.*, 60 F.3d 153, 156 (3d Cir. 1995) (citation omitted); *see also, e.g., Carnathan v. Ohio Nat'l Life Ins. Co.*, No. 1:06-CV-999, 2008 WL 4000392, at *2 (M.D. Pa. Aug. 25, 2008) (refusing to exclude testimony where there was “no surprise or prejudice” to the opposing party). As a result, the preclusion of witness testimony at trial is typically limited to situations where sanctions for severe misconduct—such as intentional spoliation—are warranted. *See, e.g., Mosaid Techs. Inc. v. Samsung Elecs. Co.*, 348 F. Supp. 2d 332, 338 & n.11 (D.N.J. 2004) (finding that “negligent destruction of relevant evidence” may be capable of giving rise to a finding of spoliation but cannot support “imposition of . . . serious sanctions” such as the “exclusion of evidence”); *Borrell v. Bloomsburg Univ.*, No. 3:CV-12-2123, 2015 WL 3613246, at *5-6 (M.D. Pa. June 8, 2015) (declining to exclude witnesses pertinent to the case where there was no evidence of bad faith by the party seeking to present the testimony); *Jama v. Esmor Corr. Servs., Inc.*, No. 97-3093(DRD), 2007 WL 1847385, at *47-49 (D.N.J. June 25, 2007) (declining to exclude trial testimony as a sanction for alleged spoliation because there was no showing that evidence was destroyed willfully or intentionally; “[i]n deciding which sanctions are

appropriate, the court must consider that dismissal or suppression of evidence are the two most drastic sanctions and that they should only be imposed in the most extraordinary circumstances”).

Here, Plaintiffs’ three-paragraph argument regarding Dr. Lin does not even allege, much less establish, the elements necessary to prove intentional spoliation or other bad-faith misconduct. Moreover, Plaintiffs’ arguments that Dr. Lin’s testimony should be barred absent a finding of intentional or severe misconduct are legally and factually meritless.

First, Plaintiffs argue that Dr. Lin should be precluded from testifying at trial because his custodial file is allegedly “inadequate” insofar as it “contains only one document that predates December 2017.” (Pls.’ Trial Br. at 6.) This argument is baseless. Dr. Lin’s custodial file, which has long been available to Plaintiffs, contains well over 1,000 documents, including more than a dozen documents predating December 2017. This includes Dr. Lin’s handwritten notebooks about the Irbesartan Improvement Project that is the subject of the July 27, 2017 email. (See ECF [1573](#) at 10:12-19.) Further, the fact that Dr. Lin has a relatively limited number of pre-2018 documents that hit upon the valsartan-related search terms agreed to by the parties is unsurprising given Dr. Lin’s role as a chemist in CEMAT. As ZHP has repeatedly explained, neither Dr. Lin nor CEMAT (which was only established in 2014) was involved in the development, manufacture or sale of valsartan API. (See,

e.g., ECF [1485](#) at 14-15 (“[A]t the time the zinc chloride process was developed in 2011, CEMAT *did not exist.*.”).) Because Dr. Lin and CEMAT had little involvement with valsartan API or finished-dose products prior to 2018, when the NDMA impurity was identified and his department began investigating it, it is no surprise that his custodial file contains few responsive documents from the years prior to the recall. (*See* ECF [1573](#) at 10:20-11:12.)

Plaintiffs also assert—with no supporting evidence—that, because the July 27, 2017 email was not found in Dr. Lin’s custodial file at the time documents were produced in 2020-2021, ZHP must have “intended to conceal the email and any surrounding documents and communications.” (Pls.’ Trial Br. at 6 n.1.) This speculative accusation has already been rejected by the Special Master. (*See* ECF [1573](#) at 43:21-44:3 (Special Master holding that Plaintiffs “have [not] made even a preliminary showing of spoliation” based on the relatively limited number of documents related to valsartan in Dr. Lin’s files).)

Prior to the litigation hold that was put in place in connection with this litigation, ZHP maintained its records consistent with its regular retention policies. Thus, it is unsurprising that an email from 2017 would not have been found in Dr. Lin’s files years later. In any event, the July 27, 2017 email *was* produced to Plaintiffs, and the circumstances surrounding the email’s discovery and production have been explained in deposition testimony and corroborated by documentary

evidence and contemporaneous emails. (See Dep. of Min Li, Ph.D. 33:22-35:17, Apr. 20, 2021 (Ex. 1 to Cert. of Jessica Davidson (“Davidson Cert.”); ZHP02730423 (Davidson Cert. Ex. 2); ZHP02730425 (Davidson Cert. Ex. 3); ZHP02730426 (Davidson Cert. Ex. 4).) As a result, the mere fact that the July 27, 2017 email was not found in Dr. Lin’s custodial file (and was produced from another company source) cannot justify barring this critical witness’s testimony at trial. *See Masterank Wax, Inc. v. RFC Container, LLC*, No. 19-12245 (KMW/MJS), 2022 WL 19927891, at *8 (D.N.J. Aug. 30, 2022) (“The Third Circuit has, on several occasions, manifested a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony.”) (quoting *ABB Air Preheater*, 167 F.R.D. at 671).

Second, there is also no merit to Plaintiffs’ assertion that they will be prejudiced by Dr. Lin’s testimony because ZHP indicated its “intention to call [Dr. Lin] as a witness just weeks before trial.” (Pls.’ Trial Br. at 6.) ZHP timely disclosed Dr. Lin as a witness before any deadline to do so had passed and weeks before the parties submitted their March 14, 2024 Pretrial Order to the Court, in which both sides disclosed their trial witness lists. At the time, ZHP immediately offered Dr. Lin for a deposition. Plaintiffs did not respond. Plaintiffs cannot be heard to complain about insufficient time when they purposely chose not to depose Dr. Lin and thus created their own claimed prejudice.

Finally, Plaintiffs have been focused on Dr. Lin's email for almost three years, having questioned countless ZHP witnesses about it and disclosed multiple expert witnesses who offer opinions based on it. As a result, Plaintiffs' assertion that they were unfairly surprised or prejudiced by the designation of Dr. Lin lies in stark contrast to the record and facts in this case. *See DiFlorio*, 1995 WL 710592, at *2 (declining to exclude testimony and finding that any "prejudice to defendants' opportunity to prepare" could be cured where trial was "still a month away"); *Washington v. Vogel*, 880 F. Supp. 1534, 1536 (M.D. Fla. 1995) (denying motion to bar a witness from testifying based on assertion that the plaintiffs' counsel had concealed information about the witness until shortly before the parties' final pretrial statement was due, noting that "even if [p]laintiffs' counsel had engaged in improper discovery tactics, [d]efendants have failed to demonstrate that they have in fact been prejudiced"). Rather, it is clear that Plaintiffs seek to control the narrative heard by the jury about the email by preventing them from hearing the author himself.

For all of these reasons, barring ZHP from presenting Dr. Lin's testimony at trial would be unfair and erroneous.

II. MS. KONG SHOULD NOT BE BARRED FROM TESTIFYING AT TRIAL.

Plaintiffs also argue that because ZHP previously objected to the production of Maggie Kong's custodial file on relevance and privilege grounds in the context of a narrow discovery dispute, it should be judicially estopped from presenting *any*

testimony from her at trial. (*See* Pls.’ Trial Br. at 1.) As this Court has recognized, however, a party’s “judicial estoppel argument fails” where the opponent “did not succeed in” pressing its prior position. *See Wood v. Borough of Lawnsdale*, No. 08-2914 (RBK/AMD), 2009 U.S. Dist. LEXIS 89909, at *13-14 (D.N.J. Sept. 28, 2009) (Kugler, J.) (plaintiff’s “judicial estoppel argument fails because the Borough did not succeed in its prior suit in arguing that CFBL lacked standing to pursue Ms. Wood’s claim”); *see also Creely v. Genesis Health Ventures, Inc.*, 184 F. App’x 197, 201 (3d Cir. 2006) (because party “did not succeed in its [prior] argument . . . judicial estoppel does not foreclose [related party’s] current position”). Because ZHP’s objection to discovery from Ms. Kong was overruled and materials from her custodial files were produced to Plaintiffs years ago, judicial estoppel does not apply.

In any event, there is nothing inconsistent about ZHP’s decision to bring Ms. Kong to testify at trial. As Plaintiffs expressly acknowledge, ZHP represented in the course of a discovery dispute that Ms. Kong had “no direct role in the *development, manufacturing, testing or sale of valsartan*” and that many of the documents in Ms. Kong’s custodial file would involve communications “with the ZHP Parties’ attorneys.” (Pls.’ Trial Br. at 2-3 (emphasis added) (quoting ECF [1485](#) at 16-17).) By contrast, ZHP seeks to elicit testimony from Ms. Kong at trial regarding non-privileged matters relevant to Plaintiffs’ expected trial presentation about which she *does* have personal knowledge. This includes, but is not limited to, the events

immediately leading up to and following the voluntary recall of valsartan, including ZHP's communications with pharmaceutical clients, the procurement of testing materials, and the organization of manpower to test batches of valsartan to confirm the alleged presence of nitrosamines and collect information to be passed on to regulators, pharmaceutical clients and the public at large. (Pls.' Trial Br. at 4.) Ms. Kong also has personal knowledge of ZHP's reaction to the recall, the effect of the recall on the company, and the steps taken to ensure the safety of valsartan so that it could be returned to the market in order to provide much-needed anti-hypertension treatment to patients.

Notably, these recall and post-recall-related subjects were not addressed in the parties' 2021 dispute regarding the production of Ms. Kong's custodial file because they were, at most, peripheral to the production-related issues that were the focus of the parties' narrow discovery dispute at that time. Indeed, it only became clear recently that Plaintiffs intend to make the promptness of ZHP's voluntary recall following the discovery of nitrosamines in valsartan in 2018 a major theory of their case, particularly with respect to their request for punitive damages. (*See, e.g.*, Joint Final Pretrial Order at 6 (Plaintiffs asserting in the summary of their case for trial that "ZHP unreasonably delayed" the recall and "attempted to persuade the FDA to agree to allow ZHP and others to continue to sell" valsartan that was eventually recalled).) Because such allegations concern activities in which Ms. Kong did have

a direct role, her testimony would be relevant, and ZHP has a right to present her at trial.

CONCLUSION

For the reasons set forth above, the Court should reject Plaintiffs' request to bar ZHP from presenting Dr. Jinsheng Lin and Maggie Kong as fact witnesses at trial.

Dated: September 24, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 24, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
Jessica Davidson